

## **REMARKS**

This amendment is submitted in response to the non-final Office Action mailed February 12, 2007 (“Office Action”). After entry of this amendment, claims 19-40 will be pending. Claims 19 and 37 are independent. In the Office Action, the Examiner:

- rejected claims 19 and 37 under 35 U.S.C. § 103(a) (“Section 103(a)”) as unpatentable over U.S. Pat. No. 5,032,125 to Durham *et al.* (“Durham”);
- rejected claims 19-25, 27, 31, 34-38, and 40 under Section 103(a) as unpatentable over Durham in view of U.S. Pat. No. 5,454,813 to Lawes (“Lawes”);
- rejected claim 27 under Section 103(a) as unpatentable over Durham in view of Lawes further in view of U.S. Pat. No. 6,648,889 to Bramlet *et al.* (“Bramlet”);
- rejected claims 28 and 29 under Section 103(a) as unpatentable over Durham in view of Lawes further in view of U.S. Pat. No. 4,432,358 to Fixel (“Fixel”);
- rejected claims 30, 32, and 39 under Section 103(a) as unpatentable over Durham in view of Lawes further in view of U.S. Pat. No. 5,908,422 to Bresina (“Bresina”); and
- rejected claim 33 under Section 103(a) as unpatentable over Durham in view of Lawes further in view of Bresina further in view of U.S. Pat. No. 6,187,007 to Frigg *et al.* (“Frigg”).

Claim 37 has been amended to correct a formal matter. Line 4 of claim 37 now refers to “the first longitudinal axis” recited in line 2 of claim 37 rather than to “the central longitudinal axis.” No new matter has been added by this amendment.

### ***Rejections under Section 103(a)***

Claims 19-40 are rejected under Section 103(a) as unpatentable over Durham and/or as unpatentable over Durham in view of one or more of Lawes, Bramlet, Fixel, Bresina, and Frigg. These rejections are respectfully traversed.

Independent claim 19 recites “a sliding sleeve . . . configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve.” Independent claim 37 recites a “bone fixation element . . . configured and dimensioned for free rotation within the central bore of the sliding sleeve.” Durham does not disclose, teach, or suggest a bone fixation element that can freely rotate relative to a sleeve.

Instead, Durham teaches that flat surfaces 44 of bore 42 of sleeve 40 cooperate with flat surfaces 66 of body member 62 of lag screw 60 in order to “prevent lag screw 60 from rotating within sleeve 40.” (Col. 3, line 56 – col. 4, line 5.) The Examiner argues that Durham states that the flat surfaces on the sleeve are preferable, and that therefore they are not critical to operation of the device and it would be obvious to make the inner profile of Durham circular. Applicant respectfully disagrees. Modifying Durham to allow the lag screw to rotate within the sleeve would render the device unsatisfactory for its intended purpose. MPEP § 2143.01(V) states: “If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” To successfully treat the femoral neck fractures discussed in Durham (*see, e.g.*, Abstract), a device must prevent rotation of the femoral head with respect to the rest of the femur. Flat surfaces 44 and 46, which prevent rotation of lag screw 60 within sleeve 40, work along with set screw 80, which prevents rotation of sleeve 40 within passage 28 (col. 4, line 67 – col. 5, line 3), to ensure that the femoral head cannot rotate with respect to the rest of the femur. If lag screw 60 were allowed to rotate within sleeve 40, this requirement would no longer be met, and the device of Durham would no longer be suited for its purpose of treating femoral neck fractures. Therefore, there is no suggestion or motivation to modify Durham to allow lag screw 60 to rotate within sleeve 40, and it would not be obvious to a person having ordinary skill in the art to do so. Additionally, Lawes, Bramlet, Fixel, Bresina, and Frigg do not remedy this deficiency of Durham, as none discloses, teaches, or suggests a bone fixation element that freely rotates relative to a sleeve.

Further, claims 19 and 37 recite a “locking mechanism configured and adapted to selectively lock rotation of the bone fixation element relative to the sleeve when in a first position and permit free rotation of the bone fixation element relative to the sleeve when in a second position.” Durham does not disclose, teach, or suggest a locking mechanism as recited in claims 19 and 37. Further, it would not be obvious to one having ordinary skill in the art to modify Durham to include such a locking mechanism. As explained, in Durham, lag screw 60 and sleeve 40 are keyed to always prevent rotation of lag screw 60 relative to sleeve 40. Lawes, Bramlet, Fixel, Bresina, and Frigg, each of which either discloses a screw that can never rotate with respect to a sleeve or does not disclose a sleeve at all, do not remedy this deficiency of Durham. Durham, Lawes, Bramlet, Fixel, Bresina, and Frigg, alone or in combination, fail to disclose, teach, or suggest a locking mechanism as claimed.

Additionally, claims 19 and 37 recite a “sliding sleeve,” *i.e.*, a sleeve adapted to slide with respect to an intramedullary pin. Durham does not disclose, teach, or suggest “a sliding sleeve.” Instead, Durham uses set screw 60 to “secure sleeve 40 within passage 28” of rod 20. (Col. 4, line 67 to col. 5, line 3.) Set screw 60 not only prevents sleeve 40 from moving axially within passage 28, but it also prevents sleeve 40 from rotating within passage 28. If set screw were to be removed, the device of Durham would no longer work for its intended function, because sleeve 40, and hence screw 60, would then be able to rotate with respect to passage 28. This would in turn permit rotation of the femoral head with respect to the rest of the femur, an occurrence to be avoided in treating femoral neck fractures. Therefore, it would not be obvious to one having ordinary skill in the art to modify Durham to allow for axial movement of sleeve 40 with respect to passage 28 of rod 20. *See MPEP § 2143.01(V).*

Therefore, Applicants respectfully request that the rejection of independent claims 19 and 37 be withdrawn. Because each of dependent claims 20-36 and 38-40 depend from either claim 19 or claim 37, Applicants respectfully request that the rejections of claims 20-36 and 38-40 be withdrawn for at least the same reasons that the rejections of independent claims 19 and 37 should be withdrawn.

Additionally, claim 20 recites that “the bone fixation element, sliding sleeve and locking mechanism are adapted for insertion through the transverse opening in the pin as a single preassembled unit.” Similarly, claim 38 recites that “the cross-member[, which comprises a bone fixation element, a sliding sleeve, and a locking mechanism,] is adapted for insertion through the transverse opening in the pin as a single preassembled unit.” The Examiner relies on Durham for disclosure of these claim elements. (Office Action at 3.) However, Durham does not disclose, teach, or suggest a fixation element, sliding sleeve, and locking mechanism adapted for insertion as a preassembled unit. Instead, Durham teaches installing lag screw 60 prior to sleeve 40. (Col. 4, lines 59-67.) In fact, installing lag screw 60 at the same time as sleeve 40 is impossible with the device of Durham. As discussed above, lag screw 60 cannot rotate relative to sleeve 40. Therefore, if one attempted to insert lag screw 60 along with sleeve 40, it would be impossible to screw in lag screw 60. Thus, it would not be obvious to one having ordinary skill in the art to modify Durham to insert the lag screw 60 in a preassembled unit also including sleeve 40 because doing so would render Durham unfit for its intended purpose. *See MPEP § 2143.01(V).* Lawes, Bramlet, Fixel, Bresina, and Frigg, each of which either discloses a screw that cannot rotate with respect to a sleeve or does not disclose a sleeve at all, do not remedy this deficiency of Durham. Durham,

Lawes, Bramlet, Fixel, Bresina, and Frigg, alone or in combination, fail to disclose, teach, or suggest a fixation element, sliding sleeve, and locking mechanism adapted for insertion as a preassembled unit. Thus, Applicant respectfully submits that the rejections of claims 20 and 38 should be withdrawn for this additional reason.

**CONCLUSION**

It is believed that claims 19-40 are in condition for allowance. Should the Examiner not agree with any of Applicants' positions or arguments herein, a telephonic or personal interview is respectfully requested to discuss and resolve any remaining issues.

No fee is believed due for this response. Should any fee(s) be due at this time, please charge such fee(s) to Jones Day Deposit Acct. No. 50-3013.

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Respectfully submitted,

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